REMARKS

Claims 1-2, 5-16, 18-19, 25-33, 35-37 and 41-44 are pending and under examination in the subject application.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-2, 5-19, 25-33, 35-37 and 41-44 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement for the full breadth of the claims. The Examiner indicated that the specification is enabling for a method of treating and/or imaging melanin containing melanoma in a subject comprising administering an amount of a radiolabeled antimelanin antibody, wherein the antimelanin antibody is 6D2.

The Examiner also indicated that applicants' previous Declaration under 37 C.F.R. §1.132 presented *in vitro* data with radiolabeled anti-melanin monoclonal antibody 11B11, while the claims are directed to *in vivo* treatment and imaging, and thus the data presented in the previous Declaration do not appear to be commensurate in scope with the claimed invention.

In reply, applicants would first like to respectfully point out that it is well recognized that *in vitro* data can support *in vivo* applications (*In re Brana,* 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); MPEP §2164.02). Furthermore, it has been acknowledged that it would not require undue experimentation to obtain antibodies needed to practice an invention (*In re Wands,* 858 F.2d 731, 8 USPQ2d 1400, 1407 (Fed. Cir. 1988); MPEP §2164.01(a)).

In addition, applicants would like to direct the Examiner's attention to an additional Declaration of Ekaterina Dadachova under 37 C.F.R. §1.132 (3 pages), which is attached hereto. In the Declaration, Dr. Dadachova describes additional *in vivo* data in support of the present invention, which were obtained with the anti-melanin monoclonal antibody 11B11 labeled with 188-Rhenium.

As described in the Declaration, monoclonal antibody (mAb) 11B11 was generated by immunizing BALB/c mice with purified *Cryptococcus neoformans* melanin followed by fusion of splenocytes to myeloma cells (Rosas AL, Nosanchuk JD, Feldmesser M, Cox GM, McDade HC, Casadevall A. Synthesis of polymerized melanin by *Cryptococcus neoformans* in infected rodents. *Infect. Immun.* 68(5):2845-53, 2000, of record). The purified antibody was obtained from supernatant made by growing the 11B11 hybridoma cells in standard DMEM with 5% FCS. The antibody was captured on a column using agarose beads with anti-mouse IgM (Sigma) and eluted using acid then neutralized (pH 7). The antibody concentration was determined by ELISA by comparison to a commercial standard.

For radioimmunotherapy (RIT) studies, 12 week-old female nude mice were implanted subcutaneously with 8 x $10^6$ A2058 human metastatic melanoma cells into the left flank and used for therapeutic experiments 12 days after tumors reached the size of approximately 0.15 $cm^3$ (0.02-0.4 $cm^3$). The mice were randomized into three groups of 5. The RIT group received IP 1 mCi dose of $^{188}$Re-11B11 (100 μg) ("hot" mAb). The control groups received either 100 μg of unlabeled ("cold") 11B11 IP or PBS. 11B11 was radiolabeled with $^{188}$Re "directly" as described in the present application. Mice were weighed and tumor volumes were measured immediately before administration of radiolabeled mAb and every 3-4 days thereafter. Tumors were measured in three dimensions with calipers, and tumor volume was calculated by multiplying the product of the three perpendicular diameters by 0.5, assuming an elliptical geometry.

The results are illustrated in the figure in the Declaration. The figure presents the change in tumors volume with Vo being a tumor volume on the day of treatment, and Vt the tumor volume on the day of measurement. This demonstrates that radiolabeled 11B11 melanin-binding mAb is therapeutic in the highly aggressive and slightly melanized experimental human metastatic melanoma.

These additional data provide further support for applicants' position that the specification is enabling for the skilled artisan to practice the claimed invention without undue experimentation.

Reconsideration and withdrawal of this ground of rejection are respectfully requested.

Rejections under 35 U.S.C. §102(a)

Claims 1, 2, 5, 6, 9-11, 14, 16, 19, 33, 35-36 and 41-44 are rejected under 35 U.S.C. §102(a) as anticipated by Dadachova E., Shi L. and Casadevall A., Radioimmunotherapy of Pigmented Melanoma with Melanin-Targeting Antibody, in 9th Conference on Cancer Therapy with Antibodies & Immunoconjugates, Abstract P-08, October 2002.

Applicants respectfully traverse this rejection.

The cited Dadachova et al. Abstract was published in October 2002, which is less than one year before the February 11, 2003 filing date of priority document U.S. Provisional Patent Application No. 60/446,684.

As set forth in the second attached Declaration of Ekaterina Dadachova under 35 U.S.C. §1.132 (2 pages), Dadachova et al. (2002) is authored by two co-inventors (E. Dadachova and A. Casadevall) and a technician (L. Shi). The third co-inventor, Joshua D. Nosanchuk, was listed as an author when the Abstract was submitted to the meeting organizers; however, his name was mistakenly omitted as an author from the published version of the Abstract. L. Shi, who was a technician working under the direction of Joshua D. Nosanchuk, was included as an author on the 2002 Dadachova et al. Abstract because she assisted in performing experiments reported in the Abstract. L. Shi did not contribute to the conception of the invention claimed in the present application.

Therefore, the present invention was *not* described in the October 2002 Dadachova et al. Abstract *before* the invention thereof by the applicants. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. §103(a)

Claims 7-8, 12-13 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dadachova E., Shi L. and Casadevall A., Radioimmunotherapy of Pigmented Melanoma with Melanin-Targeting Antibody, in 9th Conference on Cancer Therapy with Antibodies & Immunoconjugates, Abstract P-08, October 2002, in view of Rodwell et al. (U.S. Patent No. 5.047,227).

Claims 18 and 25-27 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dadachova E., Shi L. and Casadevall A., Radioimmunotherapy of Pigmented Melanoma with Melanin-Targeting Antibody, in 9th Conference on Cancer Therapy with Antibodies & Immunoconjugates, Abstract P-08, October 2002, in view of Rodwell et al. (U.S. Patent No. 5.047,227), in further view of Kobayashi et l. (Cancer Research 56: 3788-3795, 1996.

Reconsideration and withdrawal of these rejections are respectfully requested in view of the remarks made hereinabove and attached Declaration concerning the October 2002 Dadachova et al. Abstract.

Supplemental Information Disclosure Statement

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the reference that is listed on the attached Form PTO/SB/08A. The listed reference is the publication of U.S. Patent Application No. 11/201,394, which is a continuation-in-part of the subject application.

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## CONCLUSIONS

In view of the remarks made hereinabove and the two enclosed Declarations, reconsideration and withdrawal of the rejections in the June 27, 2007 Office Action and passage of the pending claims to allowance are respectfully requested. If there are any minor matters preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

A check is enclosed for $705.00 for (1) the $525.00 fee for a three month extension of time for a small entity and (2) the $180.00 fee for filing an Information Disclosure Statement. No additional fee is deemed necessary in connection with the filing of this Communication. However, if any other fee is required with this submission or to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

Respectfully submitted,

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Dated: December 19, 2007
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By _____
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